K071675

Bio-Rad Laboratories
Liquichek Tumor Markers Control
Premarket Notification Section 510(k)

JUL 31 2007

1.0 DEVICE INFORMATION

Product Name:	Liquichek Tumor Markers Control
Common Name:	Clinical Chemistry Test Systems Quality control material (assayed and unassayed).

2.0 MEDICAL DEVICE ESTABLISHMENT

Manufacturing Facility:	Bio-Rad Laboratories
Address:	9500 Jeronimo Road Irvine, California 92618
Telephone:	949-598-1200
Fax:	949-598-1557

Establishment Registration No.: 2016706

3.0 DEVICE CLASS

Classification:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

4.0 PERFORMANCE STANDARDS

None Require

5.0 PROPOSED LABELING

Included in this 510(k) notification is a copy of the proposed Liquichek Tumor Markers Control vial, box and insert labels (Appendices 3, 4 and 5).

6.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE

Liquichek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. This control is substantially equivalent to the following quality control material that is currently in the market:

Lyphochek Tumor Markers Control
Bio-Rad Laboratories
Irvine, California 92618

510 (k) Number: K011579

A copy of the product insert for the above product can be found in Appendix 7.

7.0 COMPARISON OF THE NEW DEVICE WITH THE PREDICATE DEVICE

Liquichek Tumor Markers Control claims substantial equivalence to the Lyphochek Tumor Markers Control currently in commercial distribution (K011579).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Liquichek Tumor Markers Control (New Device)	Bio-Rad Laboratories Lyphochek Tumor Markers Control (Predicate Device (K011579)
Similarities		
Intended Use	Liquichek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Differences		
Form	Liquid	Lyophilized
Matrix	Human and animal serum albumin	Human serum
Levels	Level 1, 2 and 3	Level 1 and 2
Preservatives	Contains preservatives	Does not contains preservatives
Storage (Unopened)	-20°C to -70°C. Until expiration date	2°C to 8°C Until expiration date
Open Vial Claim / After reconstitution	All analytes 30 days at 2 to 8°C, Exceptions: ▪ Insulin-like Growth Factor-I (IGF-1) 15 days.	All analytes 14 days at 2 to 8°C Exceptions: ▪ Ferritin and CA 27-29 6 days. ▪ ACTH, Free PSA, PSA, Calcitonin assay immediately.
After reconstituting and freezing	No claims	30 days at -10 to -20°C.
Analytes	Contains claim for the following: ▪ Alpha Fetoprotein ▪ Beta-2-Microglobulin ▪ CA 15-3 ▪ CA 19-9 ▪ CA 27.29 ▪ CA 125 ▪ CEA ▪ Ferritin ▪ hCG (β-hCG, Total hCG, Intact hCG) ▪ PAP ▪ Prolactin ▪ Total PSA ▪ Free PSA ▪ Thyroglobulin ▪ Insulin-like Growth Factor-I	Contains claim for the following: ▪ Alpha Fetoprotein ▪ Beta-2-Microglobulin ▪ CA 15-3 ▪ CA 19-9 ▪ CA 27-29 ▪ CA 72-4 ▪ CA 125 ▪ CEA ▪ CYFRA 21-1 ▪ Ferritin ▪ hCG hCG – Beta Subunit ▪ PAP ▪ Prolactin ▪ PSA ▪ Free PSA ▪ Aldosterone ▪ ACTH ▪ CA 50 ▪ CASA ▪ Neuron Specific Enolase ▪ Calcitonin
	Does not contain claim for the following: ▪ Aldosterone ▪ ACTH ▪ CA 50 ▪ CASA ▪ Neuron Specific Enolase	Does not contain claim for the following: ▪ Thyroglobulin ▪ Insulin-like Growth Factor-I

8.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for this control. Product claims are as follows:

- Open vial Stability: All analytes will be stable for 30 days at 2 to 8°C, with the following exception: Insulin-like Growth Factor-I (IGF-1) will be stable for 15 days.
- Shelf Life: 2 Years at -20°C to -70°C

All supporting data is retained on file at Bio-Rad Laboratories.

Attachment 2

Liquichek Tumor Markers Control
Summary of Safety and Effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bio-Rad Laboratories
c/o Ms. Maria Zeballos
Regulatory Affairs Specialist
9500 Jeronimo Rd.
Irvine, CA 92618-2017

JUL 3 1 2007

Re: k071675
Trade/Device Name: Liquichek Tumor Markers Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: June 15, 2007
Received: June 19, 2007

Dear Ms. Zeballos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071675

Device Name: **Liquichek Tumor Markers Control**

Indications For Use: **Liquichek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K071675